



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,746	04/27/2006	Arata Toshimitsu	KUZ0030US.NP	2861

26259 7590 11/30/2007
LICATA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT	PAPER NUMBER
----------	--------------

1618

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

11/30/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary

Application No.

10/577,746

Applicant(s)

TOSHIMITSU ET AL.

Examiner

GiGi Huang

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/27/2006.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. The amendment filed 9/7/2007 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 1 and 9-10 have been amended.
 - (B) Claims 13-22 have been added.
 - (C) Comments regarding Office Action have been provided drawn to:
 - a. 112, Second Paragraph rejections for claims 9 and 10, which have been withdrawn for the reasons of record.
 - b. 102(b) rejection, by Terahara et al. which has been maintained for claims 11-12 for the reasons of record.
 - c. 102 (b) rejection, by Terahara et al. which has been withdrawn for claims 1-10 for the reasons of record.
 - d. 102 (b) rejection, by Arth et al. which has been maintained for claims 11-12 for the reasons of record.
 - e. 102 (b) rejection, by Arth et al. which has been withdrawn for claims 1-10 for the reasons of record.
2. Newly amended claims 1-10 are subject to a new matter rejection. Details are enclosed in the body of the office action.
3. Newly amended claims 1-10 are subject to as 112, Second Paragraph rejection. Details are enclosed in the body of the office action.
4. Claims 1-22 are pending in the case.

5. Claims 13-22 are withdrawn from examination being drawn to the non-elected invention due to original presentation. Details are enclosed in the body of the office action.
6. Claims 1-12 are present for examination.
7. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

Election/Restrictions

8. Newly submitted claims 13-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims are drawn to methods of reducing the side effects from transdermal preparations containing pergolide and/or a pharmaceutically acceptable salt. The claims in the original presentation were solely drawn to the composition of the preparation. The newly added claims would have been subject to a restriction if originally presented due to the different search, parameters, burden, and that other preparation would produce the same results.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection to claims 1-10.

Claims 1-10 now draw to a transdermal preparation containing 9-50 mass% of pergolide and/or a pharmaceutically acceptable salt. There is no support for the range 9-50 mass% in the specification. There is only support for the range 0.5-50 mass% on Page 15, paragraph 22 and Page 16, paragraph 22. There is an example on Page 24 where pergolide mesylate is at 9%, but this only provides a single data point in a wide range. This does not show support for the range 9-50 mass% nor would it be sufficient had the range been 0.5-9 mass%. There are no additional examples to support an additional point to limit the ranges. Thereby the only support present is a *range* of 0.5-50 mass% or a *single* point of 9%.

Claims 1-10 are thereby rejected on the grounds of new matter and written description.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

12. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "mass%" is a relative term that renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requested degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear if the term is to the total mass of the adhesive layer of the preparation, the total mass of entire transdermal preparation, the total mass of an adhesive layer on a transdermal patch, or it is the total mass which is variable if the preparation is an adhesive gel without any patch, backing or membrane. It does not allow one of skill in the art to ascertain the metes and bounds of the invention.

Claims 1-10 are rejected.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1-12 rejected under 35 U.S.C. 102(a) as being anticipated by Terahara et al. (WO 2003/013611 – please note that citations will be referenced to U.S. Patent Publication # 2004/0241240, the national stage of the WIPO document and a certified transition).

Terahara et al. teaches an adhesive pharmaceutical preparation for transdermal absorption of drugs comprising acrylic polymers and (meta)acrylic polymers (including Eudragit ® and DURO-TAK ® adhesives), drugs, penetration enhancers, plasticizers, rubber polymers, releasing paper (for transdermal patch), resins, antioxidants, filler and many other components for transdermal patches that are known in the art.

Terahara teaches the hydrophobic polymer can be a mixture of two or more species (such as TSR with Eudragit ® and DURO-TAK ® adhesives) in the amount of 10-90 mass%, most preferably 30-70 mass% based on the total composition mass.

Terahara teaches the drug to be with an ergoline skeleton and/or its salt (specifically pergolide mesylate), in an amount of preferably 0.1-50 mass% based on the mass of the total composition in the adhesive layer (Abstract, Page 1, paragraph 10-17, Page 2, paragraph 29-37, Page 3, paragraph 37-38, 40-41, 43-45, Page 4, paragraph 49-50, claims 1-2, 6-7).

Terahara teaches is a specific example of a transdermal adhesive patch comprising pergolide mesylate at 9 % (by mass), styrene-isoprene-styrene block copolymer (SIS) at 15% (by mass), TSR (acrylate copolymer), and resin. The composition was made, placed on releasing paper as the adhesive layer, and affixed with a backing (Page 4, Example 1, paragraph 49-50).

The type of metabolites, plasma levels, and AUC ratio of the claims is a limitation is in a patentable sense, but only requires that the composition has ability to so perform. As the compositions are nearly identical and the percentages for the pergolide salt are

identical, the expected metabolite formation, plasma levels, and AUC ratios would inherently be met.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terahara et al (WO 2002/038139 – please note that citations will be referenced to U.S. Patent Publication # 2004/0028724, the national stage of the WIPO document and a certified transition).

Terahara et al. teaches an adhesive pharmaceutical preparation for transdermal absorption of drugs comprising a polymer, drug, penetration enhancers, plasticizers, rubber polymers, releasing paper (for transdermal patch), resins, antioxidants, filler and many other components for transdermal patches that are known in the art (Abstract, Page 1, paragraph 7-9, Page 2, paragraph 10-12, 15, 21-22, Page 3, paragraph 23-24, 27-29, 31-32, Page 4, paragraph 34, 41-45, claims 1-8).

Terahara teaches is a specific example of a transdermal adhesive patch for pergolide mesilate (same as pergolide mesylate) that is comprised of Eudragit ® (a methacrylate/methacrylic copolymer), acrylate polymer (DÜRO-TAK ®387-2287), resin,

and alcohol. The composition was made, placed on releasing paper as the adhesive layer, and affixed with a backing (Page 5, Example 5, paragraph 56-57). The amount of pergolide mesilate is 9% and the amount of styrene-isoprene-styrene block copolymer (SIS) is 4.7%. Terahara also teaches that the styrene-isoprene-styrene block copolymer (SIS) can be used in combination and the desirable amount of the rubber polymer is from 5-60%, but is preferably 10-50%, and *most* preferably from 20-40% by weight based on the whole amount of the adhesive layer.

The type of metabolites, plasma levels, and AUC ratio of the claims is a limitation is in a patentable sense, but only requires that ability to so perform. As the compositions are nearly identical and the percentages for the pergolide salt are identical, the expected metabolite formation, plasma levels, and AUC ratios would inherently be met.

Terahara et al. does not expressly teach the incorporation of SIS at 10-70%.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust and modify the amount of SIS, as suggested by Terahara, and produce the instant invention. Terahara explicitly teaches that the preferred amount, if not the most preferred amount, of SIS is preferably 10-50%, and *most* preferably from 20-40%. It would be obvious to one of skill in the art to modify and incorporate additional SIS in the composition to improved the skin permeability of the drug and/or increase the adhesive properties of the patch.

One of ordinary skill in the art would have been motivated to do this because transdermal delivery of a drug is susceptible to peeling, inadequate delivery due to poor

adhesion, and external abrasion. One would have been motivated to increase the adhesive properties by increasing the amount of rubber polymer (SIS) to ensure adhesion of the patch to the skin, and thereby improve drug delivery with is desirable.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

17. The information disclosure statement filed 4/26/2007 has been reviewed and the clarification by Applicant with respect to JP 2000-514053, JP 2002-515424, and JP 11-507361 is appreciated. The references have been considered and annotated on the IDS submitted.

18. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as failing to have sufficient antecedent basis for the limitation of "(meth)acrylic copolymer" in claim 1. Claim 1 has been amended to add the limitation of "an adhesive layer containing 10-71 mass% styrene-isoprene-styrene block copolymer". However, this does not address the lack of antecedent basis for the limitation of a "(meth)acrylic copolymer" in claims 9-10. Claims 9-10 are drawn to a (meth)acrylic copolymer in an

adhesive layer in claim 1. There is no basis for this claim as claim 1 draws to a transdermal composition containing pergolide with no reference to a (meth)acrylic copolymer, nor further limitation of the claim 1. Thereby there is no basis for the claims.

The rejection of claims 9 and 10 is maintained.

19. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as failing to have sufficient antecedent basis for the limitation of "adhesive layer" in claim 1.

Claim 1 has been amended to add the limitation of "an adhesive layer containing 10-71 mass% styrene-isoprene-styrene block copolymer". The rejection of claims 9-10 is withdrawn.

20. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as failing to have sufficient antecedent basis for the limitation of "acrylic polymer" in claim 9. Claim 10 has been amended to add the recitation to further limit the composition of the adhesive layer. The rejection of claim 10 is withdrawn.

21. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 has been amended to clarify the recitation of the acrylic polymer with respect to the (meth)acrylic copolymer. The rejection of claim 10 is withdrawn.

22. Claims 1-9, 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Terahara et al. (WO 2002/038139 – please note that citations will be referenced to U.S. Patent Publication # 2004/0028724, the national stage of the WIPO document and a certified transition).

Applicant's arguments filed 09/07/2007 with respect to claims 1-9 and 12 have been considered but are moot in view of the new grounds of rejection. The rejection of claims 1-12 under 35 U.S.C. 102(a) as being anticipated by Terahara et al. (WO 2003/013611) and under 35 U.S.C. 103(a) as being unpatentable over Terahara et al (WO 2002/038139) are addressed above.

Applicant's arguments filed 09/07/2007 on pages 3-5, with respect to claim 11 have been fully considered but they are not persuasive. Applicant's arguments against the prior art rejections of record are centered on the amendment reciting the range of 9-50 mass% of pergolide and/or a pharmaceutically acceptable salt and the range of 10-70 mass% of SIS. Neither amendment nor ranges apply in claim 11. Claim 11 only recites a transdermal preparation comprising pergolide and/or a pharmaceutically acceptable salt.

The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Terahara et al. (WO 2002/038139) is maintained.

23. Claims 1-9, 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Arth et al. (U.S. Pat. # 6,461,636).

Applicant's arguments filed 09/07/2007 with respect to claims 1-9 and 12 have been considered but are moot in view of the new grounds of rejection. The rejection of claims 1-12 under 35 U.S.C. 102(a) as being anticipated by Terahara et al. (WO 2003/013611) and under 35 U.S.C. 103(a) as being unpatentable over Terahara et al (WO 2002/038139) are addressed above.

Applicant's arguments filed 09/07/2007 on pages 3-5, with respect to claim 11 have been fully considered but they are not persuasive. Applicant's arguments against the prior art rejections of record are centered on the amendment reciting the range of 9-50 mass% of pergolide and/or a pharmaceutically acceptable salt and the range of 10-70 mass% of SIS. Neither amendment nor ranges apply in claim 11. Claim 11 only recites a transdermal preparation comprising pergolide and/or a pharmaceutically acceptable salt.

The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Arth et al. (U.S. Pat. # 6,461,636) is maintained.

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claims 1-10 and 12 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, and 13 of copending Application No. 10486425 in view of Terahara et al. (WO 2002/038139).

Claims 1, 7, and 13 of copending Application No. 10486425 are drawn to a transdermal composition comprising a drug that is pergolide mesylate, a copolymer with N-vinyl-2-pyrrolidone in a drug-containing adhesive layer with a support layer (patch).

Terahara et al. (copending Application No. 10486425) does not expressly teach the range of pergolide or SIS.

Terahara et al. (WO 2002/038139) teaches that SIS, acrylate polymers and copolymers are used in transdermal preparations and specifically with pergolide mesylate (mesylate). Terahara teaches the drug range is from 0.1-50% and a pergolide mesylate is specifically exemplified at 9%. Terahara also teaches that the SIS is preferably 10-50%, and *most* preferably from 20-40%.

It would be obvious to one of skill in the art to modify and incorporate SIS in the composition as it is commonly used to improve the skin permeability of the drug and/or increase the adhesive properties of patches. It is also obvious to incorporate the pergolide at the ranges indicated in the instant claims as exemplified by the art. It is also noted that the adjustment of ranges for SIS and the drug as taught by Terahara where the general conditions of a claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

One of ordinary skill in the art would have been motivated to do this because transdermal delivery of a drug is susceptible to peeling, inadequate delivery due to poor adhesion, and external abrasion. One would have been motivated to increase the adhesive properties by incorporating and optimizing the amount of rubber polymer (SIS) to ensure adhesion of the patch to the skin, along with the drug (pergolide) and thereby improve drug delivery with is desirable.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This is a provisional obviousness-type double patenting rejection.

26. Claims 1-10 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, and 13 of copending Application No. 10486425 in view of Terahara et al. (WO 2002/038139).

Claims 1, 6, and 8 of copending Application No. 10469612 are drawn to a transdermal composition comprising a drug including pergolide and/or a pharmaceutically acceptable salts, at least one acrylic polymer, and styrene-isoprene-styrene block copolymer in a drug-containing adhesive layer with a patch.

Terahara et al. (copending Application No. 10486425) does not expressly teach the range of pergolide or SIS.

Terahara et al. (WO 2002/038139) teaches that SIS, acrylate polymers and copolymers are used in transdermal preparations and specifically with pergolide mesilate (mesylate). Terahara teaches the drug range is from 0.1-50% and a pergolide mesilate is specifically exemplified at 9%. Terahara also teaches that the SIS is preferably 10-50%, and *most preferably* from 20-40%.

It would be obvious to one of skill in the art to modify and optimize the amount of SIS in the composition as it is commonly used to improve the skin permeability of the drug and/or increase the adhesive properties of patches. It is also obvious to incorporate the pergolide at the ranges indicated in the instant claims as exemplified by the art. It is also noted that the adjustment of ranges for SIS and the drug as taught by Terahara where the general conditions of a claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

One of ordinary skill in the art would have been motivated to do this because transdermal delivery of a drug is susceptible to peeling, inadequate delivery due to poor adhesion, and external abrasion. One would have been motivated to increase the adhesive properties by incorporating and optimizing the amount of rubber polymer (SIS) to ensure adhesion of the patch to the skin, along with the drug (pergolide) and thereby improve drug delivery with is desirable.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This is a provisional obviousness-type double patenting rejection.

27. The examiner has identified two copending Applications which have been rejected under Double Patenting above. Because of Applicant's prolific Patent and Application portfolio, the burden is shifted to Applicant to identify all relevant Applications and Patents and to include said Applications and Patents on any terminal disclaimer filed.

Conclusion

28. Claims 1-12 are rejected.

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER